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10/630,348	07/29/2003	Navin Vaya	1296-016	9293

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,348	VAYA ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5-7-08, 7-23-08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9-13,16-35,39-43 and 46-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-13,16-35,39-43 and 46-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on May 7, 2008 and the preliminary amendment filed on July 23, 2008 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-13, 16-35, 39-43, and 46-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how the high solubility of the active agent is determined. It is unclear if the active agents have a high solubility in water or a different medium.

It is further unclear what the units of measure for ratios presented are in. The examiner has interpreted the ratios to be weight ratios.

Regarding claims 3-5, 11, 28, 33, 35, 41, and 47, it is unclear what Applicant is claiming by ammonio methacrylate copolymers type A and B as described in the USP and methacrylic acid copolymer type A, B, and C, as described in the USP, polyacrylate dispersion 30% as described in Ph.Eur. The claims must be presented to define the invention within the metes and bounds of the specification. The citation to outside sources is outside the specification.

Regarding claim 21, it is unclear what applicant is claiming by "the high solubility active ingredient is potent". The examiner has interpreted the claim to be medically effective. Clarification is requested.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 25 recites the broad recitation can be given twice a day or more, and the claim also recites preferably can be given once day which is the narrower statement of the range/limitation.

Claim 28 contains the trademark/trade name Eudragit RS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any

particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the polymer ammonio methacrylate copolymer type A and B and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 9-13, 16-23, 25-26, 30-35, 39-43, and 46-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (US Patent 6,600,300).

Timmins discloses a controlled release delivery system for pharmaceuticals which have high water solubility, such as antidiabetic metformin HCl salt. The delivery system includes (1) an inner solid particulate phase formed of substantially uniform granules containing a pharmaceutical having a high water solubility, and one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more hydrophobic materials such as one or more waxes, fatty alcohols and/or fatty acid esters, and (2) an outer solid continuous phase in which the above granules of inner solid particulate phase are embedded and dispersed throughout, the outer solid continuous phase including one or more hydrophobic polymers, one or more hydrophobic polymers and/or one or more hydrophobic materials such as one or more

waxes, fatty alcohols and/or fatty acid esters, which may be compressed into tablets (abstract). Timmins discloses high water solubility to be solubility in water at ambient temperature of at least about 50mg/mL water (column 9, lines 40-46).

The inner solid particulate phase may comprise 10-98% drug (column 9, lines 59-61). The extended release material in the form of hydrophobic polymers and/or other hydrophobic materials is in the range of about 5-95% by weight, based on the weight of the inner solid particulate phase (column 9, lines 62-67), which reads on the claimed weight ratio of drug: polymer particles of 100:2.5 to 100:30 as recited in the instant claims.

The inner solid particulate phase is in a weight ratio to the outer solid continuous phase is within the range of 0.5:1 to 4:1 (column 9, lines 54-58), which reads on the claimed weight ratio of particles: coating of 100:2.5 to 100:30 as recited in the instant claims.

Regarding claims 3-5, 11, 33-35, 41, hydrophobic polymers which may be employed in the inner solid particulate phase and/or outer solid continuous phase include, but are not limited to ethyl cellulose, hydroxyethylcellulose, ammonio methacrylate copolymer, methacrylic acid copolymers, methacrylic acid-acrylic acid ethyl ester copolymer, methacrylic acid esters neutral copolymer, dimethylaminoethylmethacrylate-methacrylic acid esters copolymer, vinyl methyl ether/maleic anhydride copolymers, their salts and esters (column 10, lines 44-55).

Regarding claims 10, 40, and 49-50 highly water soluble drugs, such as metformin, will be employed in a dosage range of 150-3000mg on a regimen in single daily doses or 2-4 divided daily doses, 1-4 times a day (column 20, lines 21-28).

Regarding claims 12-13 and 42-43, other hydrophobic materials which may be employed in the inner solid particulate phase and/or outer solid continuous phase include, but are not limited to waxes such as beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate, glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate, and hydrogenated castor oil (column 10, lines 56-65).

Regarding claim 19 and 48, Applicants attention is drawn to the table on the top of column 21 and Examples 1-4, which discloses 28-39% released at 1 hour, and between 75.7 through 93.1 at 6hrs (columns 21-23: Examples 1-4).

Since the prior art discloses the same composition as the instant claims, it is the position of the examiner that it would possess the same functional properties at the instant claims, with regard to plasma concentrations.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have optimized the ratio of particles to coating in order to alter the drug release profile. Timmins discloses, in a controlled release dosage form, the formulator tries to reduce the rate of dissolution by, for example, embedding the drug in a polymeric matrix or surrounding it with a polymeric barrier membrane through which

drug must diffuse to be released for absorption. To reduce the rate of release of drug from the dosage form to an appropriate level consistent with the blood level profile desired for a drug possessing very high water solubility, very large amounts of polymer would be required for the matrix or barrier membrane. If the total daily dose of drug to be delivered is of the order of only a few milligrams this may be feasible, but many drugs having the solubility properties described require total daily doses of the order of many hundreds of milligrams. Whilst it is possible to create oral controlled release dosage forms for such products by use of large amounts of polymer, an unacceptably large dosage form may result (column 2, lines 16-33).

Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). The optimization of the polymer coating would be a rate limiting/controlling variable.

Claims 24, 27-28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (US Patent 6,600,300) in view of Merck Index citations for niacin, sodium valproate, and nicotine.

The teachings of Timmins is disclosed above and applied in the same manner.

Timmins does not particularly disclose the use of niacin, sodium valproate, or one of the compounds disclosed in instant claim 24.

The Merck Index provides the following solubility's:

Niacin: One gram dissolves in 60 ml water.

Sodium valproate: One gram is sol in 0.4 ml water

Nicotine: Very sol in water.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted any highly soluble drug into the formulation of Timmins since Timmins discloses that any highly soluble drug is usable. One of ordinary skill would have the expectation of success since Timmins discloses numerous others highly water soluble drugs as well.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615